

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

KAID C. MUSGRAVE, et al.,

Plaintiffs,

v.

**BREG, INC. AND LMA,
NORTH AMERICA, Inc., et al.,**

Defendants.

Case No. 2:09-cv-01029

JUDGE GREGORY L. FROST

Magistrate Judge Mark R. Abel

OPINION AND ORDER

This matter is before the Court on Breg, Inc.'s Motion *in Limine* to Exclude Improper Testimony of Peggy Pence, Ph.D. (ECF No. 154) and Plaintiffs' Memorandum in Support of their Opposition to Defendant's Motion to Exclude Improper Testimony of Peggy Pence, Ph.D. (ECF No. 161). For the reasons that follow, the Court **DENIES AS MOOT IN PART AND DENIES IN PART** Breg's motion.

I. Background

Plaintiff Kaid C. Musgrave was seventeen years old in 2003 when he injured his right shoulder during a high school football game. On November 4, 2003, Dr. Brad E. Brautigan performed arthroscopic surgery on Musgrave's shoulder at the Zanesville Surgery Center in Zanesville, Ohio. After the surgery, Dr. Brautigan prescribed and implanted the catheter of a Breg infusion pain pump to administer local anesthetic for post-operative pain control. Dr. Brautigan used a Breg PainCare 3200 and placed the catheter intra-articularly, *i.e.*, inside the shoulder joint. Dr. Brautigan prescribed 0.5% Marcaine (an anesthetic known generically as bupivacaine) for use in the pump. The pain pump was removed two days later, on November 6,

2003.

Musgrave continued to experience problems with his right shoulder, and on December 17, 2004, underwent a second arthroscopic surgery. During this surgery, Dr. Brautigan observed osteoarthritic changes to the glenohumeral joint. Less than two years after using the Breg pain pump, Musgrave developed chondrolysis, which is the rapid loss of joint cartilage following some chemical, mechanical, infectious, immunological, or thermal insult. *See* Daniel J. Soloman, *et al.*, Glenohumeral Chondrolysis After Arthroscopy: A Systematic Review of Potential Contributors and Causal Pathways, *Arthroscopy* 25:11:1329 (2009). The result of this cartilage loss is a joint that no longer has a smooth gliding surface to cover the ends of the bone, so the joint rubs bone against bone causing pain and stiffness. Due to this condition, Musgrave underwent a total right shoulder arthroplasty. He has a complete loss of cartilage in his shoulder and degenerative bone loss.

Musgrave and his parents (together “Plaintiffs”) filed this action on November 13, 2009. Plaintiffs claim that the post-operative continuous injection of anesthetics directly into Musgrave’s shoulder joint caused chondrolysis, leaving him with serious and permanent cartilage damage. Plaintiffs’ complaint contains claims for relief against Breg for products liability, based on Breg’s alleged inadequate warning regarding intra-articular injection of anesthetics and/or use of the pain pump after orthopedic surgery, the Breg PainCare 3200 pain pump’s alleged defective design, and Breg’s alleged breaches of express and implied warranties. Plaintiffs also alleged claims for common law fraud and punitive damages.

On September 2, 2011, this Court granted Breg’s Motion for Summary Judgment as it related to Plaintiffs’ common law breach of implied and/or express warranty claims and denied

the remainder of Breg's motion.

II. Standard

Although neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize the Court to rule on an evidentiary motion *in limine*, the United States Supreme Court has noted that the practice of ruling on such motions “has developed pursuant to the district court’s inherent authority to manage the course of trials.” *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). The purpose of a motion *in limine* is to allow the Court to rule on issues pertaining to evidence in advance of trial in order to avoid delay and ensure an even-handed and expeditious trial. *See Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004) (citing *Jonasson v. Lutheran Child & Family Servs.*, 115 F.3d 436, 440 (7th Cir. 1997)).

Courts, however, are generally reluctant to grant broad exclusions of evidence *in limine*, because “a court is almost always better situated during the actual trial to assess the value and utility of evidence.” *Koch v. Koch Indus., Inc.*, 2 F. Supp.2d 1385, 1388 (D. Kan 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). To obtain the exclusion of evidence under such a motion, a party must prove that the evidence is clearly inadmissible on all potential grounds. *See Ind. Ins. Co.*, 326 F. Supp. 2d at 846; *Koch*, 2 F. Supp. 2d at 1388; *Cf. Luce*, 469 U.S. at 41. “Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.” *Ind. Ins. Co.*, 326 F. Supp.2d at 846. Denial of a motion *in limine* does not necessarily mean that all evidence contemplated by the motion will be admitted at trial. Denial merely means that without the context of trial, the Court is unable to determine whether the evidence in question should be excluded. *Id.* The Court will entertain

objections on individual proffers as they arise at trial, even though the proffer falls within the scope of a denied motion *in limine*. *Id.* (citing *United States v. Connelly*, 874 F.2d 412, 416 (7th Cir.1989); *Luce*, 469 U.S. at 4). Consequently, the Court declines to make a definitive pretrial ruling under Federal Rule of Evidence 103(a) as requested by Breg.

III. Discussion

In Breg's motion, it requests exclusion of one of Plaintiffs' expert's opinions pursuant to Federal Rule of Evidence 702 and the test set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The United States Supreme Court held in *Daubert* that the Federal Rules of Evidence had superseded the "general acceptance" test of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and that Rule 702 requires that trial judges perform a "gate-keeping role" when considering the admissibility of expert testimony. *Daubert*, 509 U.S. at 597. Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Further, the Supreme Court has made clear that Rule 702 applies not only to scientific testimony but also to other types of expert testimony based on technical or other specialized knowledge. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147, 149 (1999).

The trial court's gate-keeping role is two-fold. First, a court must determine whether the proffered testimony is reliable. *See Daubert*, 509 U.S. at 590. The reliability assessment focuses on whether the reasoning or methodology underlying the testimony is scientifically valid. *Id.*

The expert's testimony must be grounded in the methods and procedures of science and must be more than unsupported speculation or subjective belief. *Id.* Thus, the proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3rd Cir. 1994).

The Supreme Court in *Daubert* set out four non-exclusive factors to aid in the determination of whether an expert's methodology is reliable: (1) whether the theory or technique has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the method used and the existence and maintenance of standards controlling the technique's operation; and (4) whether the theory or method has been generally accepted by the scientific community. *Daubert*, 509 U.S. at 593-94. *See also Deal v. Hamilton County Bd. of Ed.*, 392 F.3d 840, 851 (6th Cir. 2004). The Court in *Kumho Tire* stressed that, in assessing the reliability of expert testimony, whether scientific or otherwise, the trial judge may consider one or more of the *Daubert* factors when doing so will help determine that expert's reliability. *Kumho Tire*, 526 U.S. at 150. The test of reliability is a "flexible" one, however, and the four *Daubert* factors do not constitute a "definitive checklist or test" but must be tailored to the facts of the particular case. *Id.* (quoting *Daubert*, 509 U.S. at 593); *see also Ellis v. Gallatin Steel Co.*, 390 F.3d 461, 470 (6th Cir. 2004). The particular factors will depend upon the unique circumstances of the expert testimony involved. *See Kumho Tire Co.*, 526 U.S. at 151-52.

The second prong of the gate-keeping role requires an analysis of whether the expert's reasoning or methodology can be properly applied to the facts at issue, that is, whether the

opinion is relevant to the facts at issue. *See Daubert*, 509 U.S. at 591-93. This relevance requirement ensures that there is a “fit” between the testimony and the issue to be resolved by the trial. *See United States v. Bonds*, 12 F.3d 540, 555 (6th Cir. 1993). Thus, an expert’s testimony is admissible under Rule 702 if it is predicated upon a reliable foundation and is relevant.

The gatekeeper role, however, is not intended to supplant the adversary system or the role of the jury; rather, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596. The judge’s role is simply to keep unreliable and irrelevant information from the jury because of its inability to assist in factual determinations, its potential to create confusion, and its lack of probative value. *Wellman v. Norfolk and W. Ry. Co.*, 98 F. Supp. 2d 919, 923-24 (S.D. Ohio 2000).

In the instant action, Breg argues Plaintiffs’ expert Peggy Pence, Ph.D. should be prohibited from: (1) construing federal law and concluding that Breg violated it; (2) offering narrative histories that consist of reading and interpreting documents that jurors can evaluate for themselves; (3) speculating as to Breg’s motive and intent; (4) effectively instructing the jury to find Breg liable by opining that Breg violated the “standard of care,” which she never defines or supports by citation to any objective reference; (5) confusing and misleading the jury by opining about events and conduct that post-date Kaid Musgrave’s surgery, or (6) opining to the jury that Breg’s alleged conduct in promoting its infusion pumps is the equivalent of the “illegal and fraudulent promotion scheme” described by the US attorney in connection with the criminal prosecution of a different company (Pfizer) regarding a different product (the prescription drug

Neurontin).

Initially, the Court notes that Plaintiffs have confirmed that they do not intend to have Dr. Pence offer testimony regarding Pfizer or the Neurontin litigation. Consequently, the Court **DENIES AS MOOT** that portion of Breg's motion.

Breg also argues that Dr. Pence should not be permitted to testify that "Breg knowingly took part in an illegal scheme," or that its actions were "fraudulent," and that Dr. Pence should be precluded from "drawing inferences about Breg's supposed intent from the evidence" or implicitly commenting on the credibility of Breg's witnesses. (ECF No. 154-1 at 9). Plaintiffs submit, however, that Dr. Pence will not testify to the ultimate conclusions on whether Breg committed fraud nor will she be testifying to the intent of Breg or its employees. Accordingly, the Court **DENIES AS MOOT** that portion of Breg's motion.

With regard Dr. Pence's expected testimony related to actions that post-dated Kaid Musgrave's surgery, Breg indicates that it incorporates "by reference the arguments, authorities, and evidence set out in and attached to its "Motion *in Limine* to Exclude Documents and Testimony Regarding Actions That Post-Date Pump Usage." (ECF No. 154-1 at 13) (referring to ECF Nos. 155, 155-1.) The Court has issued its decision on that motion, which is hereby incorporated herein. (ECF No. 174.) Consequently, the Court **DENIES** the portion of Breg's motion related to Dr. Pence testifying about documents created post-surgery.

As to Dr. Pence's expected causation testimony, if any, Breg states that:

On September 2, 2011, this Court denied Breg's *Daubert* motions challenging the reliability of Plaintiffs' proof of general and specific causation. Breg will not repeat its arguments here; however, for purposes of the record, Breg incorporates herein by reference the arguments, authorities, and evidence set out in and attached to its Motions to Exclude the Causation Testimony of Mark R. Hutchinson, M.D., Joseph P. Iannotti, M.D., PH.D, Stephen F. Badylak, D.V.M., M.D., and Martin T. Wells,

Ph.D, and all evidence in support of those motions. Breg urges the same objections set out in those motions with respect to the opinions of Dr. Pence to the extent that they rest on the assumption that intra-articular infusion of Marcaine in the dose and for the duration at issue in this case can cause chondrolysis (general cause) or did cause Kaid Musgrave's alleged chondrolysis (specific cause).

(ECF No. 154-1 at 13.) For the same reasons the Court denied Breg's *Daubert* motions related to these other experts' testimony on general and specific causation, the Court **DENIES** that portion of Breg's current motion. The Court hereby incorporates its decisions on those motions herein. (ECF No. 151 denying ECF Nos. 104, 105, 106, 108.)

As to the remaining testimony expected from Dr. Pence, as Plaintiffs correctly point out, at least three courts have evaluated the propriety of that testimony in pain pump cases, and all have permitted her to testify. In *Schott v. I-Flow Corp.*, 696 F. Supp.2d 898 (S.D. Ohio 2010), the Honorable S. Arthur Spiegel denied the defendant's motion to exclude the testimony of Dr. Pence. In doing so, he noted that Dr. Pence's testimony "could assist the jury in understanding the complex regulatory scheme applicable to medical devices." *Id.* at 905. Judge Spiegel went on to say that "Plaintiffs do not offer her testimony as an opinion on the ultimate issue of Ohio law, whether Defendant failed to adequately warn about its product, and therefore Defendant's objections are lacking in merit." *Id.*

Similarly, in denying the defendant pain pump manufacturers' motion to exclude Dr. Pence's testimony, a trial court in Indiana found that the testimony of Dr. Pence, which relied upon "relevant literature, internal I-Flow documents, government documents and deposition testimony[,] . . . could assist the jury in understanding the complex regulatory scheme applicable to medical devices." *Paugh v. I-Flow Corp.*, No. 32D02-0802-CT-9, slip op. at *6 (Ind. Sup. Ct. April 19, 2010).

In another pain pump case, a federal district court in Illinois explained that “whether I-Flow violated federal regulations is not an ultimate issue of law in this case, and therefore Dr. Pence can offer testimony on this question.” *Smith v. I-Flow Corption*, No. 09-C-3908, slip op. at *11, (N.D. Ill. May 3, 2011) (citing to, *inter alia*, *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 164, 192 n.16 (S.D.N.Y. 2009) (“The cases in this [multi-district litigation] are not governed by federal regulations but by state law theories of negligence and strict liability. Expert testimony on regulatory compliance will assist the jury in determining whether Merck acted as a reasonably prudent pharmaceutical manufacturer”)).

For the same reasons these three courts found that Dr. Pence’s testimony to be admissible under Federal Rule of Evidence 702 and *Daubert*, this Court finds her testimony admissible. Accordingly, the Court **DENIES** Breg’s motion as it relates to the remainder of Dr. Pence’s testimony.

IV. Conclusion

For the reasons set forth above, the Court **DENIES AS MOOT IN PART AND DENIES IN PART** Breg, Inc.’s Motion *in Limine* to Exclude Improper Testimony of Peggy Pence, Ph.D. (ECF No. 154.) As with all *in limine* decisions, these rulings are subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

/s/ Gregory L. Frost
GREGORY L. FROST
UNITED STATES DISTRICT JUDGE